

REMARKS

Entry of the foregoing amendments and reconsideration of this application are respectfully requested in view of the following remarks. Claims 4-7 and 12-31 are pending in the application, with claims 15, 21, 25, and 33-35 being the independent claims. Claims 4-7 and 12-24 are amended herein. Claims 25-35 have been added. The Applicants respectfully submit that these amendments and new claims introduce no new matter. Based on the above Amendments and the following Remarks, the Applicants respectfully request that the Examiner reconsider and withdraw all outstanding rejections.

Interview Summary

On behalf of the Applicants, the undersigned wishes to express appreciation to Examiner Clow for the courtesies extended during the interview conducted on April 4, 2006. During the interview, Applicants' representatives discussed proposed amendments to the pending claims to address the rejections under §§ 101 and 112, 2nd paragraph, and discussed the applied references. The Examiner indicated that the proposed claim amendments overcame the rejections and that the amended claims distinguished over the cited art.

Claim Objection

The Examiner objected to claim 15 for the spelling error "form" instead of "from." Claim 15 has been amended to make the required correction.

The Claims Are Directed to Patentable Subject Matter and are Definite

Claims 1-24 were rejected under 35 U.S.C. §§ 101 and 112, 1st paragraph as not being supported by a specific asserted utility or a well-established utility. Independent claims 1 and 8 have been canceled, rendering moot the rejections of those claims.

Independent claims 15 and 21 have been amended to be more specifically directed to the utility of testing or quality control for a bioassay. In particular, these claims have been amended to recite “determining a degree of error in the bioassay process based on a distance in the n-dimensional space between the test centroid and the control centroid.” In the interview, the Examiner indicated that such amendments would overcome the rejection under §§ 101 and 112, 1st paragraph.

New independent claims 25 and 35 are similarly directed to a quality control method for a bioassay and recite “determining a degree of error between the test spectral data and the control spectral data.” The Examiner also indicated that this claim was directed to patentable subject matter. Similarly, new independent claims 33 and 34 are directed to a quality control method for a bioassay and recite “comparing the test centroid to the control centroid to determine the displacement in n-dimensional space of the test centroid from the control centroid; wherein the magnitude of the displacement is an indicator of the quality of the test spectral data” and “comparing the test centroid to the control centroid to determine the displacement in n-dimensional space of the test centroid from the control centroid; wherein the magnitude of the displacement is an indicator as to whether the apparatus that generates the test spectral data should be recalibrated to reduce the displacement,” respectively.

Claims 1-24 were also rejected under 35 U.S.C. § 112, 2nd paragraph as being indefinite. The Examiner specifically identified claims 1, 8, 11, 12, and 15 as requiring clarification. The rejections based on claims 1, 8, and 11 have been mooted by the cancellation of those claims. Claim 12 has been amended to eliminate the phrase “the centroid defining the predetermined model,” which was the basis for the Examiner’s rejection.

The amendment to independent claim 15 identified above addresses the Examiner’s concern that claim 15 did not include a step of testing a bioassay against a control. In the

interview, the Examiner indicated that such amendment would overcome the rejection under § 112, 2nd paragraph.

Support for the amendments to independent claims 15 and 21 and for new claim 25 may be found in the provisional and pending utility applications. The following sentences provide citations to the provisional and pending utility applications where support may be found for certain claim phrases. These are meant to provide an example where support for such phrases may be found and are not meant to provide a complete listing of all locations within the applications where support for such phrases may be found. The phrase “quality control” is supported in the title of the provisional (*i.e.*, “Quality Assurance”); and the phrase “spectral data” is supported at page 2, Para #2 which refers to “[a]nalyze spectra” as well as at page 3, Para #9 which discusses “mass spectral data.” The elements of claim 25 that relate to providing and comparing centroids in n-dimensional space are generally supported in the provisional, for example, at page 2, Para #2 which explains that if a batch of chips “is consistent then the spectra should all map to the same cluster...” And the use of these claim elements is described in greater detail by reference at Page 2, Para #1 to a co-pending U.S. application directed to the “KDE” (*i.e.*, Knowledge Discovery Engine”) which is identified and incorporated by reference in the pending utility application at Para. 0009. Also, as recited in claim 25, the “first” and “second” aliquots are supported in the provisional at page 1, Para #6 and Para #7 which describe “sufficient volume to provide continuity over a period of several years.”

The Abstract of the pending utility application explicitly refers to “quality assurance/quality control.” The phrase “spectral data” is recited in Abstract. In the pending application, “n-dimensional space” and “control centroids” are supported at Para 0011. “Test centroids” and a comparison of the displacement of test and control centroids are supported in Para 0012, 0013, 0033 and 0036. Fig. 1 illustrates the preparation of a “mixture of molecules” and preserving “aliquots” to be used as illustrated in Fig. 2.

The phrase “determining a degree of error” is described in Para 0032 to 0034.

Additional support for new independent claims 33 and 34 is found in the pending application at Para 006 to 007 and Para 0013, which describes the accuracy of the test spectral data as being an indicator of its quality or acceptability or reliability, and also as indicating that

apparatus settings have changed or a need to recalibrate the apparatus used to generate the spectral files.

Support for new claim 32 may be found in the specification which refers, for example, to naturally occurring and artificial (*i.e.*, non-naturally occurring) molecules at Para 0020.

The elements of new independent claim 35 that relate to comparing centroids in n-dimensional space are generally supported in the provisional, for example, at page 2, Para #2 which explains that if a batch of chips “is consistent then the spectra should all map to the same cluster....”

The Claims are Allowable over the Prior Art

Claims 1-24 were rejected under 35 USC §§ 102(e) or 103(a) over US 2003/0004402 to Hitt et al. (“*Hitt*”). The Examiner also indicated in the interview that the claims as proposed to be amended distinguished over *Hitt* because the reference does not disclose or suggest the claimed subject matter. Accordingly, the Applicants respectfully submit that the claims as amended and the new claims are distinguished over *Hitt* because the reference does not disclose or suggest the claimed subject matter.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed or rendered moot. The Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding objections and rejections. Applicants believe that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that further personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

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